

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

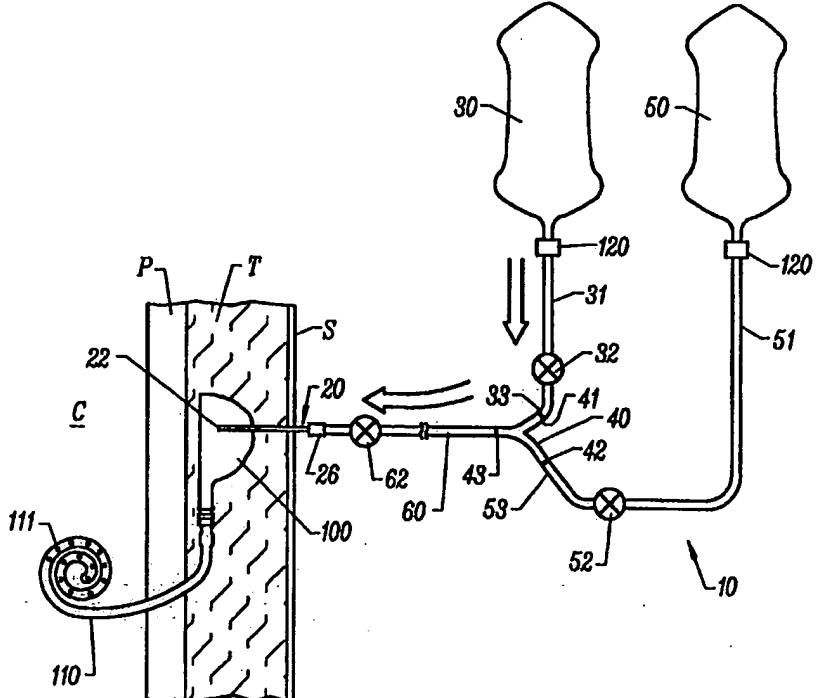
- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

**PCT**WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau

## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>6</sup>:</b> <b>A61M 5/00</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 99/03519</b> <b>(43) International Publication Date:</b> 28 January 1999 (28.01.99)
<b>(21) International Application Number:</b> PCT/US98/15360 <b>(22) International Filing Date:</b> 17 July 1998 (17.07.98) <b>(30) Priority Data:</b> 08/896,791 18 July 1997 (18.07.97) US <b>(71) Applicant:</b> VASCA, INC. [US/US]; Unit B3, 461 Boston Street, Topsfield, MA 10983 (US). <b>(72) Inventors:</b> BURBANK, Jeffrey, H.; 18 Sunrise Road, Boxford, MA 01921 (US). BRUGGER, James, M.; 5B Hillside Avenue, Newburyport, MA 01950 (US). <b>(74) Agents:</b> HESLIN, James, M. et al.; Townsend and Townsend and Crew LLP, 8th floor, Two Embarcadero Center, San Francisco, CA 94111-3834 (US).		<b>(81) Designated States:</b> AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i>
<b>(54) Title:</b> DEVICE AND METHOD FOR PERCUTANEOUS PERITONEAL DIALYSIS		
<b>(57) Abstract</b> <p>Delivering liquid compositions to an interior site in the body. More particularly, the invention provides devices, systems, and methods for facilitating percutaneous access to an implanted port for performing peritoneal dialysis in a sterile condition. In one aspect the invention provides an apparatus for use in peritoneal dialysis comprising a first container (30), and a second container (50) wherein at least one of the containers is filled with unused dialysis fluid. The first and second containers (30, 50) are fluidly coupled by a first tube (31), and a second tube (51) to a junction (40). A single common tube (60) fluidly coupled to the junction provides a fluid pathway to a percutaneous access member (20) connected to the end of the single common tube (60). The access member (20) has a minimum bore diameter of 1.16 mm capable of providing high volumetric flow rates.</p> 		

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

5

## DEVICE AND METHOD FOR PERCUTANEOUS PERITONEAL DIALYSIS

10

### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

The present invention is generally directed to delivering liquid compositions to an interior site in the body. More particularly, this invention relates to  
15 delivering and draining compositions to and from a human patient at high flow rates to perform peritoneal dialysis under sterile conditions.

Patients afflicted with end stage renal disease where kidney transplantation is unavailable may be treated  
20 by hemodialysis or peritoneal dialysis to remove toxic products from the patient's blood. Both techniques operate by the principles of diffusion across semipermeable membranes. In the case of peritoneal dialysis, the membrane that is used is the patient's  
25 peritoneal membrane. In order to perform dialysis, a dialyzing solution or dialysate is drained into the peritoneal cavity and remains in the cavity for a dwell period of usually four to six hours. The dialyzing solution typically comprises an electrolyte component to  
30 reduce loss of electrolytes and a sugar component which acts as an osmotic ingredient, removing water from the patient along with normal metabolic products such as urea, uric acid and creatinine. At the end of the dwell period, spent dialyzing solution is drained from the cavity back  
35 to the bag and the cavity refilled with fresh solution.

One serious drawback to peritoneal dialysis, which has limited its use, is that the peritoneal cavity is particularly subject to infection. Conventional peritoneal dialysis systems usually employ catheters which

are implanted transcutaneously through the patient's abdomen. This exposure naturally increases the risk of contamination through the exposed, exterior end of the catheter. The tubing sets used to infuse solution into the peritoneum may also be a source of contamination. While the use of subcutaneously implanted septum-type ports has been suggested (such ports would be accessed with needles which reduces the chance of infection), the access with small bore non-coring needles places a flow restriction in the system which reduces the flow rate below the rate achieved by transcutaneous catheters. Such small bore access needles with relatively low flow rates prolong the exchange time and create additional patient discomfort.

15

## 2. Description of the Background Art

Conventional peritoneal dialysis tubing sets and components are described in U.S. Patent Nos. 4,306,976; 4,396,382; 5,250,041; 5,334,139; 5,338,293; and 5,423,768. U.S. Patent No. 4,184,497 describes an implantable catheter having an enlarged hollow portion which can be punctured to receive a sterile access needle. U.S. Patent No. 4,496,349 describes a septum-type transcutaneous access port.

25

## SUMMARY OF THE INVENTION

The present invention is directed at reducing the time needed to exchange dialysis fluid and limiting the risk of infection to the peritoneal cavity. More particularly, the present invention allows the use of large bore, percutaneous access members to deliver and drain fluid from the peritoneal cavity at high volumetric flow rates under sterile conditions, typically above 100 ml/min, preferably 200 ml/min, or higher.

35

In a first aspect, the present invention provides an apparatus for use in peritoneal dialysis in combination with a first container and a second container.

The apparatus comprises a junction connected to a first and a second tube which are connected and/or connectable to the first and second containers, respectively. At least one of the containers is filled with unused dialysis fluid. A single common tube, fluidly coupled to the junction, fluidly connects the first and second tubes to a percutaneous access member having a bore diameter of at least 1.16 mm. Preferably, the percutaneous access member is straight and has a length in the range from about 15 mm to 40 mm, preferably from about 18 mm to 26 mm. The access member usually has a relatively large bore, typically having a lumenal diameter in the range from about 1 mm to 5 mm, preferably from about 1.5 mm to 2.1 mm. In specific embodiments of the apparatus of the present invention, the percutaneous access member comprises a large bore needle, such as a fistula-type needle. The large bore access members are advantageous in minimizing flow resistance and allowing for higher volumetric flow rates to and from the patient.

In another aspect, the present invention provides a system for performing peritoneal dialysis comprising a peritoneal dialysis tubing set having an access member and a mechanical port. The port has an aperture for receiving the access member of the tubing set and a flexible conduit in the port disposed to establish fluid flow with the access member inserted through the first passage. A linkage assembly in the port opens the flexible conduit when the access member is present in the passage and closes the flexible conduit when the access member is absent from the passage. The system may further comprise a peritoneal dialysis catheter fluidly coupled to the flexible conduit. The port allows for the advantageous use of large bore access members which would otherwise core and damage conventional septum-type ports.

In a further aspect, the present invention provides a method for performing peritoneal dialysis comprising the step of accessing a mechanical valve port

coupled to a patient with an access member. Unused dialysis solution is introduced to the patient's peritoneal cavity through the access member and the mechanical port. After the dialysis solution has been in the patient for a specified dwell period, the dialysis solution is withdrawn from the patient's peritoneal cavity through the port and the access member. Preferably, the access member has a minimum bore diameter of 1.16 mm.

These and other embodiments of the present invention, as well as its advantages and features, are described in more detail in conjunction with the text below and attached figures.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic illustration of one embodiment of the system of the present invention.

Fig. 2 illustrates a connector coupling a container and tube of the present invention.

Fig. 3 shows an alternative embodiment of a percutaneous access member of the present invention.

Fig. 4 illustrates a implantable mechanical port of the present invention, wherein the flexible conduit is adapted for connection to a separate catheter.

Fig. 5A is a side, cross-sectional view of the port of Fig. 4 shown with a closed internal valve structure.

Fig. 5B is a partial cross-sectional view taken along line 5B-5B of Fig. 5A.

Fig. 5C is a side, cross-sectional view of the port of Fig. 4 as shown with the internal valve structure opened in response to the insertion of an access needle.

Fig. 5D is a partial cross-sectional view taken along line 5D-5D of Fig. 5C.

Fig. 6 is a partial, cross-sectional view of a specific flexible conduit having a distal connector for interconnection to the proximal end of an implantable catheter.

Fig. 7 is an end view taken along line 7-7 of Fig. 6.

Fig. 8 is a schematic illustration of the system of Fig. 1 with the containers positioned to deliver and drain fluid to and from the patient.

Figs. 9-10 show a flushing step and a filling step using the system of Fig. 1.

#### DETAILED DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The present invention is generally directed to delivering liquid compositions to an interior site in the body. More particularly, the present invention provides devices, systems, and methods for facilitating percutaneous access to an implantable mechanical port for performing peritoneal dialysis in a sterile condition. Typical forms of peritoneal dialysis require the delivery and subsequent draining of a dialysis solution or dialysate from the peritoneal cavity. The dialysate typically comprises a solution which will promote diffusion or osmosis across a patient's peritoneal membrane so as to remove toxic by-products from the patient's blood. In particular forms of peritoneal dialysis such as Continuous Ambulatory Peritoneal Dialysis (CAPD), the dialysate, after initial delivery into the peritoneal cavity, remains in the cavity for a dwell period of usually 4 to 6 hours. During this time, the dialysate removes normal metabolic products such as urea, uric acid, and creatinine from the patient's body. At the conclusion of the dwell period, the used dialysate or dialysis solution is removed from the peritoneal cavity and typically replaced by a new supply of unused dialysate.

Advantageously, the ports and access systems of the present invention can achieve inflow and outflow rates as high as those achieved with transcutaneous catheters, i.e. usually about 100 ml/min, often at or above 200 ml/min. These rates are limited by



the characteristics of the peritoneal cavity itself. Prior art implanted septum ports added significant flow resistance to the access systems, usually reducing inflow and/or outflow well below 200 ml/min.

5           As shown in Fig. 1, a peritoneal dialysis tubing set 10 having a percutaneous access member 20 is used to deliver and drain the dialysate from the patient's peritoneal cavity. In preferred embodiments, the peritoneal dialysis tubing set 10 comprises at least a  
10 first container 30, a first tube 31 and a second tube 51. Optionally, a second container 50 may also be provided in the tubing set 10. The first tube 31 is connected or connectable to the first container 30 while the second tube is connected or connectable to the second container  
15 50, usually through a junction 40, which is typically a Y-type connector. As used herein after, the term Y-connector will also comprise other three-way connectors, such as T-connectors. A fluid flow controller 32 on tube 31 and a controller 52 on tube 51 regulate dialysate flow  
20 in the tubes. These fluid flow controllers 32 and 52 may completely stop fluid flow to or from their respective containers, or the fluid flow controllers may simply increase or decrease the flow rates.

          Percutaneous access member 20, typically a  
25 needle having a sharpened distal tip 22 extends from single common tube 60 which is fluidly coupled to junction 40. The access member will leave a large bore, as defined below. Access members useful in the present invention may conveniently comprise large bore coring needles, such as  
30 conventional fistula needles. By "coring needles," it is meant that the distal tip of the needle will be sharpened and will be open in a forwardly direction so that the needle is capable of cutting tissue (and "coring" septums when encountered) as it is advanced therethrough in a forwardly direction. The present invention may also  
35 utilize needles having a non-coring design, such as Huber needles which have a side-facing distal opening. The

needles will have a bore size of at least 1.16 mm (16 G), usually at least 1.33 mm (15 G), more usually at least 1.55 mm (14 G), still more usually at least 1.73 mm (13 G), and sometimes as large as 2.08 mm (12 G), or larger.

- 5 The needles may be composed of any conventional needle material, typically being a stainless steel, but could also be hard plastic.

Preferably, the access member 20 is pre-connected or permanently affixed to the single common tube 60. Optionally, a connector 26, such as a luer connector may be provided to provide for removable connection. Even when the connector 26 is provided, however, it will be preferred that the connection be made prior to packaging of the system for storage and eventual use.

- 15 Alternatively, the percutaneous access member 20 may comprise a rigid access tube that is disposed at a generally right angle relative to the distal end of the single common tube 60. Such a configuration permits the access member to be percutaneously introduced into an  
20 implanted port 100 while the single common tube 60 remains generally parallel to or flat against the patient's skin. Such a "low profile" orientation of the catheter is advantageous since it reduces the risk of dislodgement, is more comfortable to the patient, and is generally easier  
25 to accommodate in a crowded medical therapy location. Such low profile access members and further details on suitable percutaneous access members can be found in commonly assigned, co-pending U.S. Patent Application Serial No. 08/896,790, the full disclosure of which is  
30 incorporated herein by reference.

Containers 30 and 50 may be made from a flexible polymer material which can contain used or unused dialysate. Containers 30 and 50 may be made from a variety of flexible or rigid materials so long as they  
35 provide a sterile containment and storage condition when they contain unused dialysate. In preferred embodiments of the present invention, the peritoneal dialysis tubing

set 10 will typically have at least one container filled with unused dialysate, while the other container typically is empty to receive used dialysate from the patient. It is particularly critical that the container holding unused  
5 dialysate be maintained in a sterile condition in order to reduce the risk of infection to the peritoneal cavity. Sterility in the empty container which receives used dialysate is usually less critical as access to that container will be closed once the used dialysate has been  
10 drained from the patient's peritoneal cavity (discussed below). Though preferably also in a sterile condition, due to the less stringent requirements for sterility in the empty container, a greater variety of containers may be used as the empty container which receives the used  
15 dialysate.

Junction 40 comprises a three-way connector which allows the percutaneous access member 20 to be in fluid contact with either the first container 30, second container 50, or both containers simultaneously. As shown  
20 in Fig. 1, end 33 of tube 31 and end 53 of tube 51 are both connected to junction 40. In a preferred embodiment of junction 40, the junction comprises a Y-shaped connector having a first end 41 connected to end 33 of tube 31 and end 42 connected to end 53 of second tube 51.  
25 The junction 40 could comprise any other conventional three-way connector, such as a T-connector, or the like. A third end 43 of the junction 40 is fluidly coupled to single common tube 60 which leads to the percutaneous access member 20. It should be understood that a Y-shaped connector 40 could be replaced by equivalent known  
30 art devices such as particular types of directional flow valves which can selectively provide fluid access between container 30, second container 50, and percutaneous access member 20.

35 To access implantable mechanical port 100 as shown in Fig. 1, percutaneous access member 20 pierces the patient's skin S and penetrates through subcutaneous

tissue T. Optionally, the member 20 passes through a tissue tract which has been previously formed and into an aperture on the implantable port 100. Suitable methods for access the port 100 with minimal trauma are described in co-pending U.S. Patent Application Serial No. 08/896,592, the full disclosure of which was previously incorporated.

Fig. 1 depicts a specific embodiment of the implantable mechanical port 100 having a representative peritoneal catheter 110 attached to the port. The implantable port 100 according to the present invention is implanted subcutaneously a short distance beneath the surface of the patient's skin S, typically being within about 3 mm to 20 mm of the skin's surface. For purposes of peritoneal dialysis, the implantable port 100 may be located in a variety of positions within the patient's body, such as over the rib cage of the patient, in the abdominal region of the patient, or in some other location deemed appropriate by the surgeon or doctor implanting the port 100. Implantable port 100 may be subcutaneously attached to the patient using adhesives, staples, sutures, or other attachment techniques known in the art. Suitable attachment techniques and further details of an implantable mechanical valve port are described in co-pending Application Serial Nos. 60/036,124, filed on January 21, 1997; Serial No. 08/857,386, filed on May 15, 1997; and Serial No. 08/856,641, filed on May 15, 1997, each of which is assigned to the assignee of the present application. The full disclosures of each of these co-pending applications are incorporated herein by reference.

The peritoneal dialysis catheter 110 as shown in Fig. 1, passes through the peritoneum P and into the peritoneal cavity C. A specific embodiment of a peritoneal dialysis catheter, as shown in the figure, may assume a spiral configuration and have a plurality of outlet holes 111 along the length of the spiral-shaped

catheter to facilitate diffusion of the dialysate into the peritoneal cavity C. Suitable peritoneal dialysis catheters are well known in the art.

The risk of infection in the peritoneal cavity is of particular concern to those patients using peritoneal dialysis to remove toxic by-products from their body. To mitigate against infecting the peritoneum or the peritoneal cavity during dialysate transfer, all connections between first container 30, second container 50, first tube 31, second tube 51, junction 40, single common tube 60, and percutaneous access member 20 may be permanently made or pre-connected to create a closed system within the peritoneal dialysis tubing set 10 prior to use. By using sealed connections between all major elements of the tubing set 10, the entry point of infectious material is limited to access provided by the percutaneous access member 20.

In some instances, however, it may be desirable and advantageous to have releasable fluid couplings between particular elements of the tubing set 10. For example, assuming that second container 50 is the empty container receiving used dialysate from the peritoneal cavity, it may be desirable and advantageous to have a releasable fluid coupling 120 joining second tube 51 to the second container 50. Having a releasable coupling 120, as shown in Fig. 2, may allow the patient to use a greater variety of containers to contain the used dialysate as it is being drained from the peritoneal cavity C. This may provide for certain cost and manufacturing efficiencies.

In a further aspect of the invention, as shown in Fig. 3, the percutaneous access member 20 may comprise a tubular shaft 140 having a stylet 141 slidably disposed within the tubular shaft. A distal piercing end 142 on the stylet protrudes from distal end 143 of the shaft member 140 to provide percutaneous access to the implantable port 100. Once access has been achieved in

the shaft member 140 is capable of accessing the implantable port 100, the stylet 141 can be proximally withdrawn within container 144 so that the stylet 141 does not interfere with fluid flow from single common tube 60.

5 Container 144 ensures that the peritoneal dialysis tubing set 10 remains a closed system, even when stylet 141 has been proximally retracted.

Referring now to Fig. 4, an exemplary embodiment of the implantable port 100 will now be

10 described in further detail. An exemplary port 100 comprising a base 212 and flexible conduit 214 is illustrated in Figs. 4-7. As shown in Fig. 4, the flexible conduit 214 extends from the base 212 and terminates at a distal end fitting 216. Suitable conduit

15 structures are described in U.S. Patent No. 5,562,617, the full disclosure of which is incorporated herein by reference.

The fitting 216 will typically be a female fitting adapted to mate with a male fitting 218 at the

20 proximal end of a dialysis catheter 110. Of course, it should be recognized that the fitting 218 could be attached to a catheter of some other design. Provision of a connector in the cannula intermediate the port and the luminal connection has a number of benefits. The ability

25 to implant the port 100 separately from the anchored end of the cannula, and then connect, simplifies implantation. For example, it is possible to make two relatively small incisions for implanting the port 100 and attaching the cannula, respectively, and then to tunnel subcutaneously

30 to permit interconnection. Such an approach reduces patient trauma. Replacement of the port 100 and/or the cannula attachment is simplified since the two can be disconnected and one left undisturbed while the other is replaced. Such intermediate connections are preferably

35 spaced relatively close to either the port or the luminal connection, typically within 10 cm and often within 5 cm.

Referring to Fig. 5A, the base 212 of implantable port 100 comprises an upper shell 218, a base plate 220, an internal cylinder 222, and a vertically reciprocating actuator block 224 disposed within the cylinder 222. A spring 226 urges the actuator block 224 upwardly relative to the cylinder 222. When the actuator block 224 is in its upward position, the conduit 214 is pinched closed between an upper lip 228 which is a portion of the wall of cylinder 222 and a lower lip 230 which is portion of the actuator block 224 (see Fig. 5B). Proximal end of the conduit 214 is connected to the lower end of a tube 232 which depends into an interior volume of the actuator block 224. The depending tube 232 provides an axial bore 234 for receiving a percutaneous access member 20.

Referring to Fig. 5C, the access member 20 is introduced through an opening 236 at the upper end of the axial bore 234. Typically, though not necessarily, the opening 236 has a slight conical shape to facilitate alignment of the access member 20 as it is introduced into the bore 234. A pair of balls 240 are disposed in an upper portion of the tube 232 and contained within a circular aperture 242 in the shell 218 on the actuator block 224 as in its raised configuration, as shown in Fig. 5A. When access member 20 is introduced through the opening 236, it will encounter the balls 240 and depress the actuator block 224 downward until the block reaches its lower configuration. At that time, the balls 240 will move radially outward into an expanded portion 244 of the aperture 242. The balls 240 will thus become locked within the expanded region 244 so long as the access member 20 remains in place.

When the actuator block 224 has been lowered, as shown Figs. 5C and 5D, the opposed lips 228 and 230 are opened in order to relieve external clamping on the conduit 214. Thus, as the access member 20 is inserted into the implantable port 210, the clamping mechanism

which has previously closed the flexible conduit 214 will be opened. When the access member 20 is removed, the spring 226 will urge the actuator block 224 upwardly, and the implantable port will return to the configuration shown in Figs. 5A and 5B.

Referring now to Figs. 6 and 7, another alternative flexible conduit 314 which may be attached to base 212 of an implantable port 100 is illustrated. The flexible conduit 314 is formed integrally with the silicone overmolding 350, thus firmly anchoring the conduit to the base 212. While the internal portions of the conduit 314 are identical to those of conduit 214 and the earlier embodiments, the external portion of the conduit includes rib structures 318 in order to enhance hoop strength of the conduit. Moreover, a distal connector 316 is provided for connection to a male connector 320 at the proximal end of a catheter. The connector 320 comprises a metal, usually titanium, fitting which is received within the lumen of the silicone conduit 314. A clip 330 is provided for securing over the connectors 316 and 320 after the port 312 and catheter have both been implanted and connected. The catheter connection mechanism shown in Fig. 6 is particularly advantageous since the catheter may be disconnected from the flexible conduit 314 without having to disturb the implantation of the base 212 of the port 100.

A method for performing peritoneal dialysis using the peritoneal dialysis tubing set 10 of Fig. 1, will be described with reference to Figs. 1 and 8-10. The configuration of the peritoneal dialysis tubing set 10 as shown in Fig. 1, is used for filling the peritoneal cavity with unused dialysate when the cavity is empty. As there is no used dialysate to drain from the cavity, the configuration as shown does not position the empty second container 50 to receive dialysate from the patient.

Referring now to Fig. 8, the configuration of the peritoneal dialysis tubing set 10 is more typical of



what will be found when used dialysate must be drained from the peritoneal cavity and unused dialysate must be delivered to refill the cavity. Initially, percutaneous access member 20 is inserted through the skin of the patient and into an aperture in the implantable port 100 for receiving the percutaneous access member. Once the percutaneous access member 20 has been properly positioned, the member 20 will be fluidly coupled with the peritoneal dialysis catheter 110. At this stage, fluid flow controller 62 and 52 will be in an open condition so as to provide a fluid pathway between the peritoneal cavity and empty, second container 50. Fluid flow controller 32 will be in a closed condition to prevent fluid contact between unused dialysate and the used dialysate flowing from the peritoneal cavity C. Typically, drainage of the used dialysate occurs solely under the force of gravity. Alternatively, it may be possible to use a pump to increase the flow rate from the peritoneal cavity (not shown).

Once drainage of the dialysate into second container 50 has been completed, fluid flow controller 62 will be placed in a closed condition. Referring now to Fig. 9, fluid flow controller 32 will now be opened to flush portions of tube 31 and single common tube 60. Flow controller 52 will remain open during this flushing procedure, so as to allow the dialysate being flushed to flow into second container 50. It is generally understood in the art that one of the advantages of using a Y-set tubing set is that it allows for this type of flushing to remove contaminants in the flow pathway prior to filling the peritoneal cavity with unused dialysate. The flushing typically occurs for about 5 to 10 seconds.

Once the flushing has been completed, flow controller 52 will be closed, restricting access to second container 50. Flow controller 62 will now be opened to as to allow unused dialysate solution to flow from first container 30 through the tubing set 10, and eventually

into peritoneal dialysis catheter 110. The flow occurs as shown by the arrows in Fig. 10. Again, the filling process typically occurs solely under the force of gravity, although pumps or other devices may be used to assist the filling process. Once the transfer or delivery of unused dialysate into the peritoneal cavity of the patient has been completed, fluid flow controller 62 and 32 will be closed and percutaneous access member 20 will be retracted from the patient. A bandage or some other coverage device may be used to protect the percutaneous access site on the patient during the 4 to 6 hour dwell period of the dialysate within the peritoneal cavity. With the transfer of dialysate completed, the patient is free to perform daily activities without the restriction of having to carry a used dialysate container or a filtration device associated with hemodialysis.

Although the foregoing invention has been described in some detail by way of illustration and example, for purposes of clarity of understanding, it will be obvious that certain changes and modifications may be practiced within the scope of the appended claims.

WHAT IS CLAIMED IS:

1                   1.    An apparatus for use in peritoneal  
2   dialysis comprising:  
3                   a first tube fluidly coupled to a first  
4   container;  
5                   a second tube which may be fluidly coupled  
6   to a second container;  
7                   a three-way junction fluidly coupled to the  
8   ends of the first and second tubings;  
9                   a single common tube fluidly coupled to  
10   said junction and being fluidly connected to said first  
11   and second tubes through said junction; and  
12                  a percutaneous access member connected to  
13   the end of the single common tube, said member having a  
14   bore diameter of at least 1.16 mm.

1                   2.    The apparatus of claim 1, wherein the  
2   percutaneous access member is straight, has a length in  
3   the range from 15 mm to 40 mm, and a luminal diameter in  
4   the range from 1 mm to 5 mm.

1                   3.    The apparatus of claim 2, wherein the  
2   percutaneous access member is a fistula needle.

1                   4.    The apparatus of claim 2, wherein the  
2   percutaneous access member has a blunt distal tip.

1                   5.    The apparatus of claim 2, wherein the  
2   percutaneous access member comprises a tubular shaft  
3   having a stylet removably housed within the shaft.

1                   6.    The apparatus of claim 1, wherein the  
2   percutaneous access member is disposed at a generally  
3   right angle relative to a distal end of the single common  
4   tube.

1                   7. The apparatus of claim 1, wherein the  
2 percutaneous access member has a connector removably  
3 connecting the member to the single common tube.

1                   8. The apparatus of claim 1, wherein the  
2 first and second tubes each have a access member connector  
3 for removably coupling the tube to the container.

1                   9. The apparatus of claim 1, wherein the  
2 first, second, and single common tubes each have a fluid  
3 flow controller on said tubes.

1                   10. The apparatus of claim 1, further  
2 comprising a first container pre-connected to the first  
3 tube.

1                   11. The apparatus of claim 10, wherein the  
2 first container is empty.

3                   12. The apparatus of claim 11, further  
4 comprising a second container pre-connected to the second  
5 tube, wherein the second container is filled with  
6 dialysate fluid.

7                   13. The apparatus of claim 10, wherein the  
8 first container is filled with dialysate fluid.

1                   14. A system for performing peritoneal  
2 dialysis comprising:

3                   a) a peritoneal dialysis tubing set having  
4 an access member; and

5                   b) a mechanical port having  
6 a base with an aperture for receiving the  
7 access member of the tubing set,

8                   a flexible conduit in the port disposed to  
9 establish fluid flow with the access member inserted  
10 through the first passage, and

11                   a linkage assembly in the port which opens  
12 the flexible conduit when the access member is present in  
13 the passage and closes the flexible conduit when the  
14 access member is absent from the passage.

1                   15. A system of claim 14, wherein said  
2 linkage assembly comprises:  
3                   an actuator assembly reciprocatably  
4 received in the base having a bore aligned with the first  
5 passage for receiving the needle, wherein a proximal end  
6 of the flexible conduit is mechanically coupled to the  
7 bore in the actuator assembly; and  
8                   a spring for urging the actuator assembly  
9 to a first position in the base wherein the relative  
10 position of the actuator assembly and the second passage  
11 closes the flexible conduit and wherein insertion of the  
12 access tube into the first passage shifts the actuator  
13 assembly to a second position which opens the flexible  
14 conduit.

1                   16. A system of claim 14, further  
2 comprising a peritoneal dialysis catheter fluidly coupled  
3 to said flexible conduit.

1                   17. A method for performing peritoneal  
2 dialysis, said method comprising:  
3                   accessing a mechanical valve port coupled  
4 to a patient with an access member;  
5                   introducing a dialysis solution to the  
6 patient's peritoneal cavity through the access member and  
7 the implanted port, and  
8                   withdrawing the dialysis solution from the  
9 patient's peritoneal cavity through the port and the  
10 access member after a dwell period.

1                   18. A method of claim 17, wherein said  
2 access member has a minimum bore diameter of 1.16 mm.

1                   19. A method for ambulatory peritoneal  
2 dialysis comprising the steps of:

3                   providing a peritoneal dialysis tubing set  
4 having a percutaneous access member and at least two  
5 containers fluidly connected to a junction, wherein at  
6 least one of said containers is empty while the other is  
7 filled with unused dialysis fluid, and wherein said  
8 percutaneous access member has minimum bore size of 1.16  
9 mm;

10                   providing a mechanically actuated,  
11 implantable port with the patient's body, said port  
12 providing fluid access to the peritoneum of the patient;  
13                   percutaneously accessing the port with the  
14 percutaneous access member of the tubing set in order to  
15 connect the tubing set with the implantable port;

16                   emptying the peritoneal cavity of the  
17 patient of used dialysis solution by

18                   a) closing fluid access to one of said  
19 containers;

20                   b) lowering said empty container below  
21 the level of said implantable port and filling the empty  
22 container with used dialysis solution;

23                   filling the peritoneal cavity of said  
24 patient by

25                   a) closing fluid access to the  
26 container filled with used dialysis solution;

27                   b) opening fluid access from the  
28 container filled with unused dialysis fluid; and

29                   c) raising the container filled with  
30 unused dialysis fluid above the level of the implantable  
31 port.

1                   20. A method of claim 17, further  
2 comprising the step of flowing unused fluid at a minimum  
3 rate of 100 ml/min.

1                   21. The method of claim 19, further  
2 comprising the steps of:  
3                   closing fluid access to the percutaneous  
4 access member;  
5                   flushing unused dialysis fluid into the  
6 container holding used dialysis fluid prior to the filling  
7 step.

1                   22. A method as in claim 19, wherein:  
2                   the tubing set providing set further  
3 comprises a single common tube fluidly coupling the access  
4 member to the junction; and  
5                   the percutaneous access step comprises  
6 inserting the access member at an angle normal to the skin  
7 surface through which it is inserted, wherein the single  
8 common tube will lie generally flat against the skin  
9 surface.

1/8

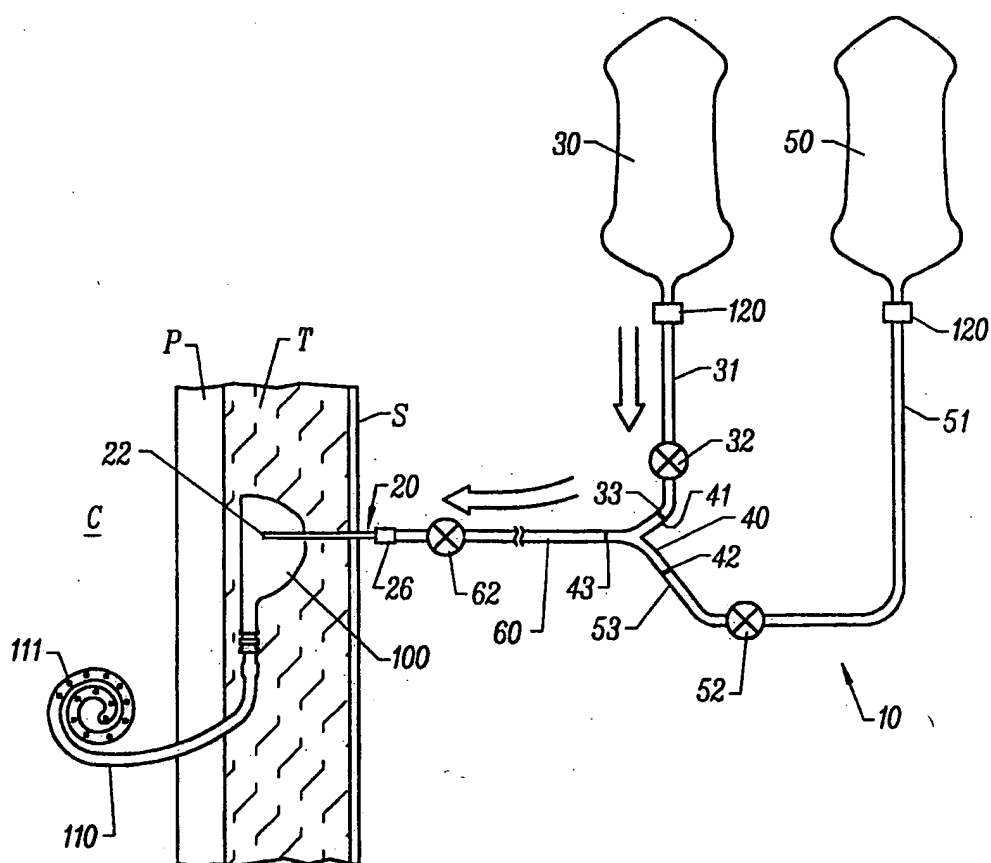
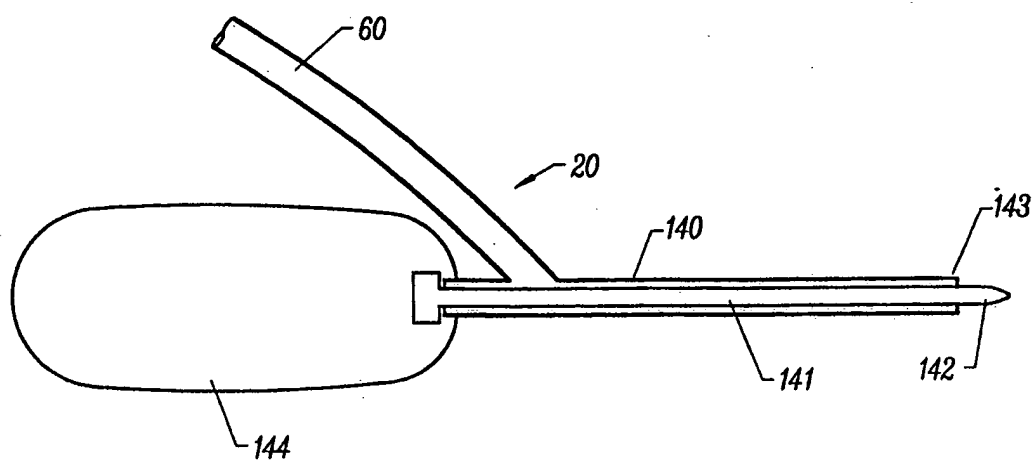
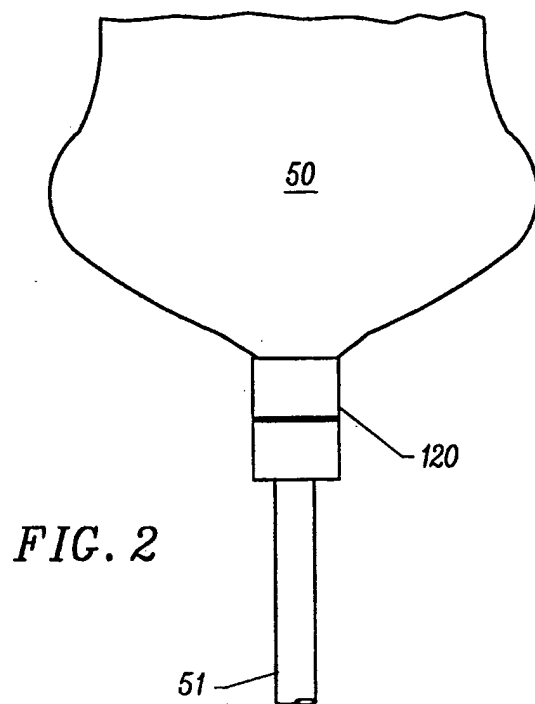


FIG. 1



2/8



3/8

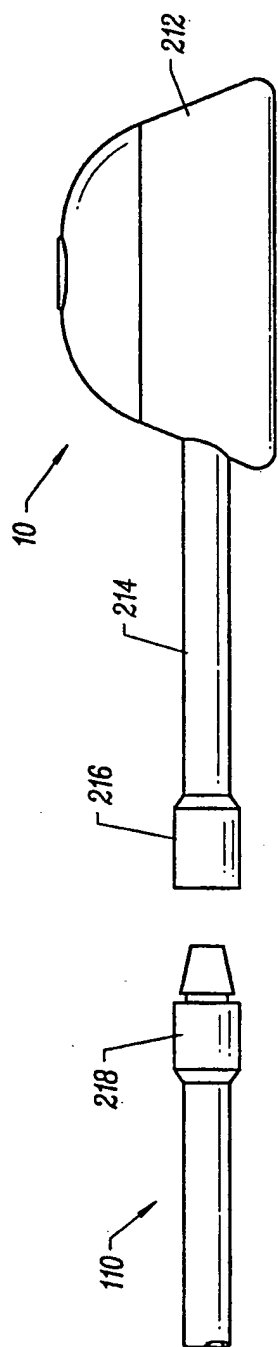


FIG. 4

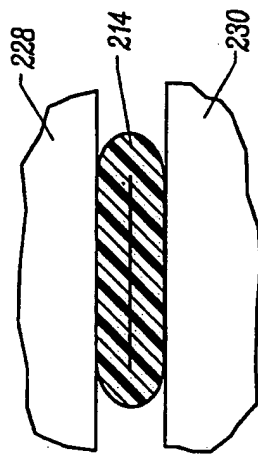


FIG. 5B

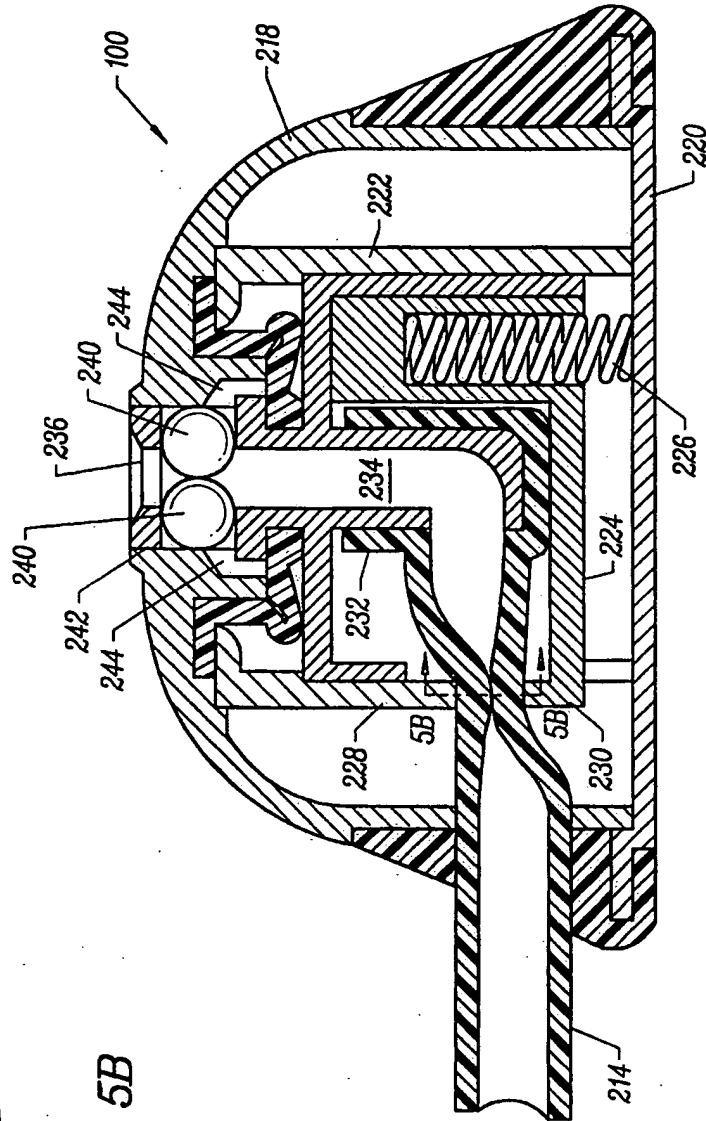
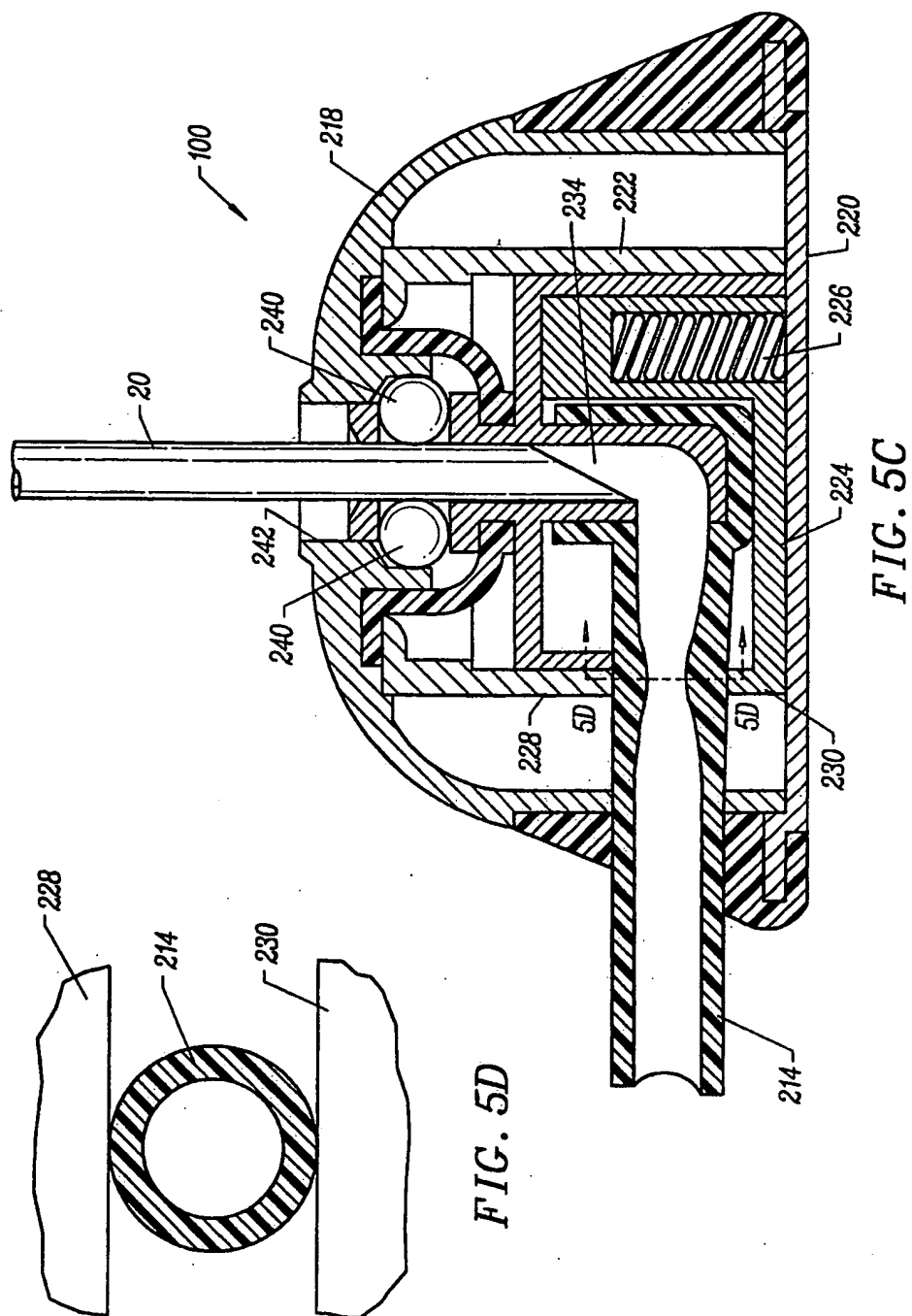
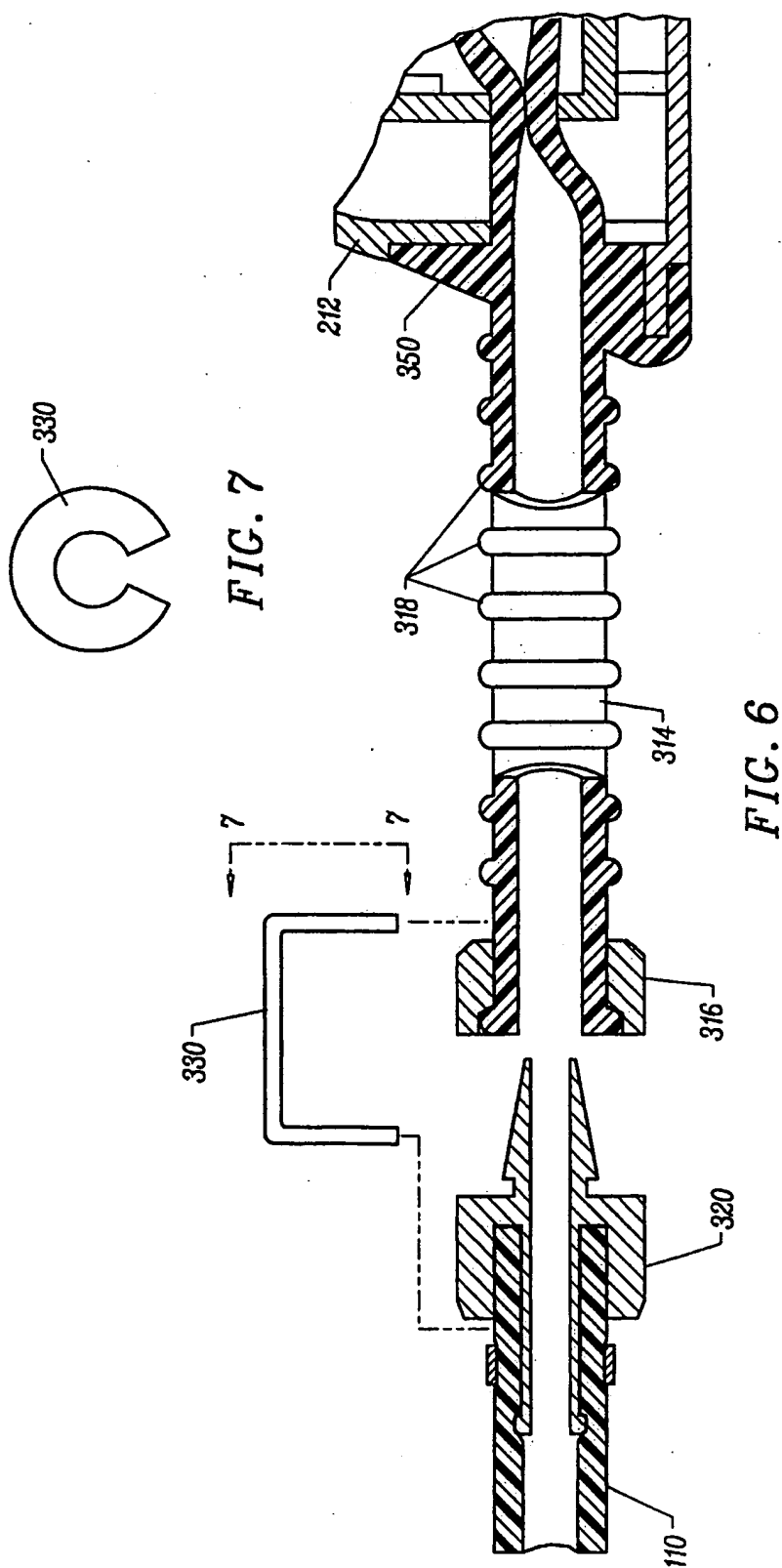


FIG. 5A





7/8.

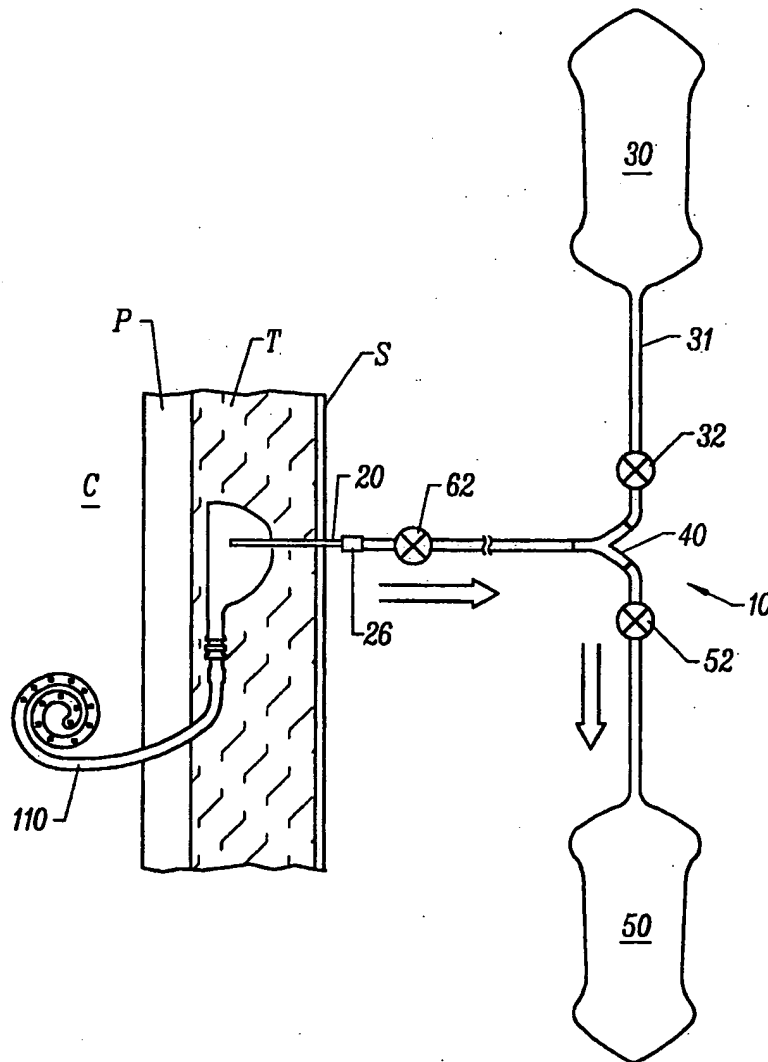


FIG. 8

8/8

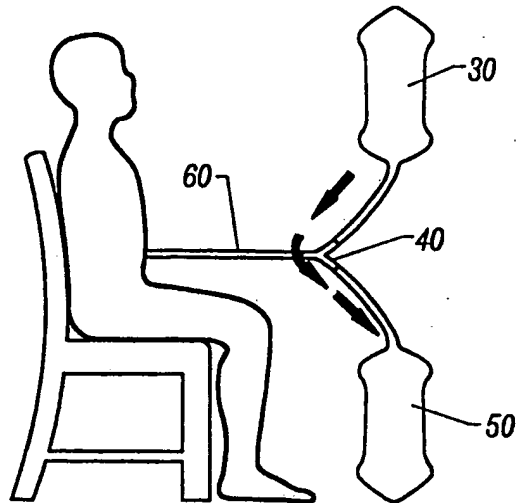


FIG. 9

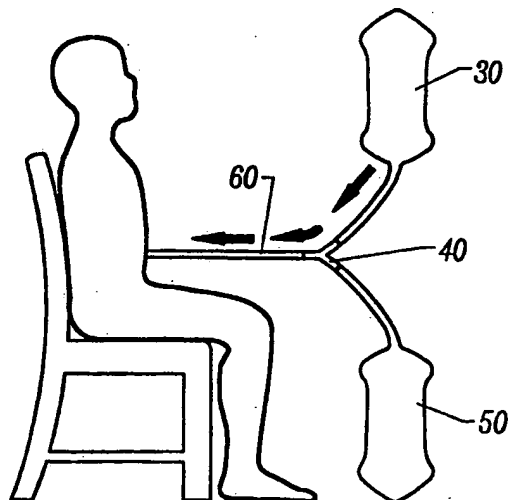


FIG. 10

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US98/15360

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(6) : A61M 5/00 US CL : 604/29 According to International Patent Classification (IPC) or to both national classification and IPC																				
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) U.S. : 251/7; 604/8, 9, 27, 28 30, 32-34, 49, 51, 93, 164, 272, 410, 891.1 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)																				
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>																				
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.																		
Y,P	US 5,782,796 A (DIN et al.) 21 July 1998 (21.07.98), Fig. 5.	1-14, 16-22																		
X	US 4,256,102 A (MONACO) 17 March 1981 (17.03.81), entire document.	17																		
---		-----																		
Y		18																		
Y	US 4,832,054 A (BARK) 23 May 1989 (23.05.89), entire document.	14																		
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.																				
<table border="0"> <tr> <td>* Special categories of cited documents:</td> <td>*T</td> <td>later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>*A* document defining the general state of the art which is not considered to be of particular relevance</td> <td>*X*</td> <td>document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>*E* earlier document published on or after the international filing date</td> <td>*Y*</td> <td>document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>*Z*</td> <td>document member of the same patent family</td> </tr> <tr> <td>*O* document referring to an oral disclosure, use, exhibition or other means</td> <td></td> <td></td> </tr> <tr> <td>*P* document published prior to the international filing date but later than the priority date claimed</td> <td></td> <td></td> </tr> </table>			* Special categories of cited documents:	*T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	*A* document defining the general state of the art which is not considered to be of particular relevance	*X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	*E* earlier document published on or after the international filing date	*Y*	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z*	document member of the same patent family	*O* document referring to an oral disclosure, use, exhibition or other means			*P* document published prior to the international filing date but later than the priority date claimed		
* Special categories of cited documents:	*T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention																		
*A* document defining the general state of the art which is not considered to be of particular relevance	*X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone																		
*E* earlier document published on or after the international filing date	*Y*	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art																		
*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z*	document member of the same patent family																		
*O* document referring to an oral disclosure, use, exhibition or other means																				
*P* document published prior to the international filing date but later than the priority date claimed																				
Date of the actual completion of the international search 26 AUGUST 1998		Date of mailing of the international search report <b>16 OCT 1998</b>																		
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230		Authorized officer SHARON ELIZABETH FINKEL Telephone No. (703) 305-0154																		